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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,307

08/07/2006

John C. Gebler

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EXAMINER

XU, XIAOYUN

ART UNIT

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1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,307	Applicant(s) GEBLER ET AL.	
	Examiner ROBERT XU	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-13,15-18,23,24,37,41,44,46,48-52,56-60,65,66,69-73,77,79,83-88,90,91 and 93.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-13,15-18,23,24,37,41,44,46,48-52,56-60,65,66,69-73,77,79,83-88,90,91 and 93.

DETAILED ACTION

1. Preliminary Amendment filed on 10/14/2005 is acknowledged. Claims 14, 19-22, 25-36, 38-40, 42, 43, 45, 47, 53-55, 61-64, 67, 68, 74-76, 78, 80-82, 89, 92 and 94-98 are cancelled. Claims 1-13, 15-18, 23, 24, 37, 41, 44, 46, 48-52, 56-60, 65, 66, 69-73, 77, 79, 83-88, 90, 91 and 93 are pending in the application and are considered on merits.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 23, 24, 37, 41, 44, 46, 48-52, 56, 57, 65, 69-73, 77, 79, and 83-88 drawn to a method of preparing a sample for mass spectrometry analysis.

Group II, claim(s) 4-8 drawn to a method of preparing a sample for mass spectrometry analysis using at least two derivative reagents.

Group III, claim(s) 9-11, 15 and 16, drawn to a method of analyzing a sample.

Group IV, claim(s) 12, 13, 17 and 18, drawn to a method of analyzing a sample using at least two derivative reagents.

Group V, claim(s) 58-60 and 93 drawn to a composition.

Group VI, claim(s) 90 and 92, drawn to a kit for use in preparing a sample for mass spectrometry analysis.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature for Groups I -VI is a triarylphosphonium labeling reagent having a reactive group capable of reacting with an exposed group of an analyte. This technical feature is known in the art, e.g. Huang et al. (Analytical Biochemistry, 1999, IDS) teaches a triarylphosphonium labeling reagent having a reactive group capable of

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reacting with an exposed group of an analyte (see abstract). Thus, the triarylphosphonium labeling reagent having a reactive group capable of reacting with an exposed group of an analyte is well known in the art, and therefore is not a special technical feature. This makes the restriction requirement proper.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Ar group is selected from the group consisting of substituted or unsubstituted aryl groups

Ar group is selected from the group consisting of substituted or unsubstituted heteroaryl groups.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Ar group is selected from the group consisting of substituted or unsubstituted aryl groups (Claim 23).

Ar group is selected from the group consisting of substituted or unsubstituted heteroaryl groups (Claim 24).

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: heteroaryl group and homoaryl group have different structures.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the exposed group of the analyte is electrophilic and the reactive functional group is nucleophilic heteroaryl group

the exposed group of the analyte is nucleophilic and the reactive functional group is electrophilic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The exposed group of the analyte is electrophilic and the reactive functional group is nucleophilic heteroaryl group (Claim 51).

The exposed group of the analyte is nucleophilic and the reactive functional group is electrophilic (Claim 52).

The following claim(s) are generic: Claim 1.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: nucleophilic is patentably distinguishable from electrophilic.

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

X⁻ is a halide, triflate, sulfate, nitrate, hydroxide, carbonate, bicarbonate, acetate, phosphate, oxalate, cyanide, alkylcarboxylate, N-hydroxysuccinimide, N-hydroxybenzotriazole, alkoxide, thioalkoxide, alkane sulfonyloxy, halogenated alkane sulfonyloxy, arylsulfonyloxy, bisulfate, oxalate, valerate, oleate, palmitate, stearate, laurate, borate, benzoate, lactate, citrate, maleate, fumarate, succinate, tartrate, naphthylate mesylate, glucoheptonate, or lactobionate.

X⁻ is an anionic Y group such that the labeling reagent is zwitterionic

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

X⁻ is a halide, triflate, sulfate, nitrate, hydroxide, carbonate, bicarbonate, acetate, phosphate, oxalate, cyanide, alkylcarboxylate, N-hydroxysuccinimide, N-hydroxybenzotriazole, alkoxide, thioalkoxide, alkane sulfonyloxy, halogenated alkane

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sulfonyloxy, arylsulfonyloxy, bisulfate, oxalate, valerate, oleate, palmitate, stearate, laurate, borate, benzoate, lactate, citrate, maleate, fumarate, succinate, tartrate, naphthylate mesylate, glucoheptonate, or lactobionate (Claim 56).

X⁻ is an anionic Y group such that the labeling reagent is zwitterionic (Claim 57).

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they have patentably distinguishable structures.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Ψ group is a carboxylic acid, a derivative of a carboxylic acid, or an activated ester of a carboxylic acid.

Ψ group is a haloalkyl, haloacetamide, halomethylbenzamide, a maleimido group, or a sulfonate ester, wherein the sulfonic acid is an alkylsulfonic acid, perfluoroalkylsulfonic acid, or an arylsulfonic acid.

Ψ group is an iodoacetamide, maleimide, or a halomethylbenzamide.

Ψ group is an isocyanate or an acyl nitrile.

Ψ group is an acyl azide, an acyl nitrile, an aldehyde, an alkyl halide, an amine, an anhydride, an aniline, an aryl halide, an azide, an aziridine, a boronate, a carboxylic acid, a diazoalkane, a haloacetamide, a hydrazine, an imido ester, an isocyanate, an isothiocyanate, a maleimide, a sulfonyl halide, or a thiol group.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Ψ group is a haloalkyl, haloacetamide, halomethylbenzamide, a maleimido group, or a sulfonate ester, wherein the sulfonic acid is an alkylsulfonic acid, perfluoroalkylsulfonic acid, or an arylsulfonic acid (Claim 70).

Ψ group is an iodoacetamide, maleimide, or a halomethylbenzamide (Claim 71).

Ψ group is an isocyanate or an acyl nitrile (Claim 72).

Ψ group is an acyl azide, an acyl nitrile, an aldehyde, an alkyl halide, an amine, an anhydride, an aniline, an aryl halide, an azide, an aziridine, a boronate, a carboxylic acid, a diazoalkane, a haloacetamide, a hydrazine, an imido ester, an isocyanate, an isothiocyanate, a maleimide, a sulfonyl halide, or a thiol group (Claim 73).

The following claim(s) are generic: Claim 65.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they have patentably distinguishable structures.

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the analyte is a protein, peptide, enzyme, immunoglobulin, hapten, antigen, amino acid, hormone, receptor, nucleic acid, hormone, chemical, polymer, pathogen, toxin, saccharide or polysaccharide, steroid, vitamin, therapeutic drug, drug of abuse,

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bacterium or virus, or a combination or fragment of any of the foregoing, or a metabolite thereof, or an antibody thereto.

the analyte is a food additive, agrichemical, surfactants, adhesives, resin, organic pollutant, or process chemical..

the analyte is a therapeutic drug or a metabolite thereof.

the analyte is a drug of abuse or a metabolite thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

the analyte is a protein, peptide, enzyme, immunoglobulin, hapten, antigen, amino acid, hormone, receptor, nucleic acid, hormone, chemical, polymer, pathogen, toxin, saccharide or polysaccharide, steroid, vitamin, therapeutic drug, drug of abuse, bacterium or virus, or a combination or fragment of any of the foregoing, or a metabolite thereof, or an antibody thereto (Claim 83).

the analyte is a food additive, agrichemical, surfactants, adhesives, resin, organic pollutant, or process chemical (Claim 84).

the analyte is a therapeutic drug or a metabolite thereof (Claim 85).

the analyte is a drug of abuse or a metabolite thereof (Claim 86).

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

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corresponding special technical features for the following reasons: they have patentably distinguishable properties.

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the sample is rainwater, or water from an ocean, river, lake, pond, or stream; the analyte is a food additive, agrichemical, surfactants, adhesives, resin, organic pollutant, or process chemical..

the sample is a biological tissue.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

the sample is rainwater, or water from an ocean, river, lake, pond, or stream; the analyte is a food additive, agrichemical, surfactants, adhesives, resin, organic pollutant, or process chemical (Claim 87).

the sample is a biological tissue (Claim 88).

The following claim(s) are generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

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corresponding special technical features for the following reasons: they have patentably distinguishable properties.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. A telephone call was made to Teresa Lauro on 06/08/2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6/9/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

RX

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